

**FOR PUBLICATION**

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

EISAI CO., LTD and EISAI, INC.,	)	
	)	Hon. Harold A. Ackerman
Plaintiffs,	)	
	)	Civil Action No. 05-5727 (HAA)
v.	)	Civil Action No. 07-5489 (HAA)
	)	
TEVA PHARMACEUTICALS USA, INC.,	)	<b><u>AMENDED OPINION</u></b>
TEVA PHARMACEUTICAL INDUSTRIES,	)	<b><u>AND ORDER</u></b> *
LTD., and GATE PHARMACEUTICALS (a	)	
division of Teva Pharmaceuticals USA, Inc.)	)	
	)	
Defendants.	)	
	)	

**ACKERMAN, Senior District Judge:**

This matter comes before the Court on appeals (Doc. Nos. 157 and 201) filed by Defendants Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries, Ltd., and Gate Pharmaceuticals (hereinafter collectively “Defendants” or “Teva”) from two orders of Magistrate Judge Esther Salas, as well as the motion for summary judgment (Doc. No. 214) filed by Plaintiffs Eisai Co., Ltd. and Eisai, Inc. (hereinafter collectively “Plaintiffs” or “Eisai”). The Complaints in these consolidated cases assert patent infringement against Teva with regard to Teva’s applications for approval to market its own generic version of Eisai’s product Aricept®, a prescription drug medication covered by U.S. Patent No. 4,895,841 (“the ‘841 patent”).

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\*This Opinion and Order amends the initial Opinion and Order issued on June 26, 2009. The Court has corrected an error in the Introduction that appeared on Page 2 of the initial Opinion and Order. The substance of the Opinion and Order remains unchanged. As reflected in the Opinion and the Court’s concluding Order, Magistrate Judge Salas’s February 13, 2008 Order is reversed, and the appealed portions of Magistrate Judge Salas’s May 29, 2008 Bench Order are vacated.

In a February 13, 2008 Order, Magistrate Judge Salas granted Eisai's motion to strike portions of Teva's Amended Answers. *Eisai Co. v. Teva Pharms. USA, Inc.*, 557 F. Supp. 2d 490 (D.N.J. 2008) (hereinafter "February Order"). Teva filed the instant appeal (Doc. No. 157) from this February Order. The February Order relied on the Magistrate Judge's December 6, 2007 Order that granted in part and denied in part Teva's motion to amend its Answer. *Eisai Co. v. Teva Pharms. USA, Inc.*, 247 F.R.D. 445 (D.N.J. 2007) (hereinafter "December Order"). Importantly, Teva did not file an appeal from the December Order.

Teva also appeals (Doc. No. 201) from two portions of a subsequent bench Order issued by Magistrate Judge Salas on May 29, 2008 ("May Bench Order") that denied some of Teva's discovery requests. These discovery requests concern the matters that Magistrate Judge Salas ordered to be stricken from Teva's Amended Answers, as well as related issues.

For the following reasons, this Court will reverse the February Order, vacate the appealed portions of the May Bench Order, and refer this matter to the Magistrate Judge for further proceedings consistent with this Opinion. This Court will stay consideration of Eisai's motion for summary judgment pending completion of any additional discovery allowed by Magistrate Judge Salas in accordance with this Opinion.

### ***Background***

#### **I. Litigation History and Teva's Motion to Amend its Answer**

In the late 1980s, Eisai developed a new drug called donepezil hydrochloride that it would eventually market as Aricept<sup>®</sup>, which is the drug claimed in Eisai's '841 patent. The '841 patent was issued on January 23, 1990, and arose from the prosecution of U.S. Patent

Application No. 07/207,339 (“the ‘339 application”). The ‘841 patent expires in November 2010.

In October 2004, Teva filed an Abbreviated New Drug Application (“ANDA”) with the Food and Drug Administration (FDA), seeking approval to market its own generic version of Aricept®. Teva’s ANDA contained a Paragraph III certification with regard to the ‘841 patent, indicating that it would not distribute its generic version prior to the patent’s expiration in November 2010. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(III).<sup>1</sup> One year after filing this ANDA, in October 2005, Teva amended its ANDA to include a Paragraph IV certification claiming that the ‘841 patent is invalid for obviousness. Shortly thereafter, Eisai filed this patent infringement suit (No. 05-5727) against Teva pursuant to 35 U.S.C. § 271(e)(2), based on Teva’s Paragraph IV certification.

Eisai’s second Complaint in this matter arose in a similar fashion. In November 2005, Defendant Gate Pharmaceuticals (“Gate”), an unincorporated division of Teva, filed an ANDA for a generic version of Aricept® with no Paragraph IV certification attacking the ‘841 patent. Nearly two years later, Gate amended its ANDA to include a Paragraph IV certification with the same claim that the ‘841 patent is invalid for obviousness. Eisai then filed a second Complaint against Defendants for patent infringement (No. 07-5489).

In Teva’s initial Answer to Eisai’s first Complaint, filed in early 2006, it asserted the

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<sup>1</sup>When submitting an ANDA to the FDA, the generic manufacturer must make one of the following four certifications with respect to each of the patents listed in the Orange Book for the drug for which the applicant seeks approval: (1) that no patent information has been filed (a “Paragraph I” certification), (2) that the patent has expired (a “Paragraph II” certification), (3) that the patent will expire on a specific date (a “Paragraph III” certification), or (4) that the patent “is invalid or will not be infringed by the manufacture, use, or sale of the drug for which the application is submitted” (a “Paragraph IV” certification). 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV).

affirmative defense of patent invalidity for obviousness. The parties extensively litigated the obviousness defense and engaged in substantial discovery relating to that defense.<sup>2</sup> More than a year later, in May 2007, Teva filed a motion to amend its Answer to add the affirmative defense of inequitable conduct. This defense amounts to an argument that the ‘841 patent is unenforceable because Eisai failed to disclose known material information to the Patent and Trademark Office (“PTO”) during the prosecution of its patent with an intent to deceive the PTO.

In its Proposed Amended Answer submitted in conjunction with the motion to amend, Teva alleged that Eisai failed to disclose four sets of its own co-pending patent applications to the PTO examiner of the ‘339 application. The majority of the inequitable conduct allegations in Teva’s Proposed Amended Answer concerned Eisai’s alleged failure to disclose a family of patent applications known as “the ‘459 application.” Eisai initially filed the ‘459 application in December 1986. While this application was pending, Eisai filed the ‘339 application in June 1988. The applications were assigned to different PTO examiners. The ‘459 application resulted in the issuance of U.S. Patent No. 4,849,431 (“the ‘431 patent”) in July 1989. The ‘339 application resulted in the issuance of the patent-in-suit, the ‘841 patent, in January 1990. Teva chiefly alleged in its Proposed Amended Answer that Eisai, in prosecuting the ‘339 application that led to the patent-in-suit, failed to disclose the co-pending ‘459 application, the ‘431 patent that issued from that application, and the existence of a 1984 article in the *Journal of Medicinal Chemistry* authored by Richard A. Kenley. Teva alleged that these materials, to which the

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<sup>2</sup>On April 16, 2007, Teva stipulated that its generic drug would constitute infringement of claims 8, 10, and 13 of the ‘841 patent, “unless Teva proves in this litigation that claims 8, 10, and 13 are invalid or unenforceable.” (Doc. No. 65.) The parties have only litigated affirmative defenses in this case.

Court will refer collectively as the “‘459 application,” were material to consideration of the ‘339 application and were withheld with the intent to deceive the PTO.

In addition to the inequitable conduct allegations regarding the ‘459 application, Teva’s Proposed Amended Answer also alleged similar inequitable conduct in Eisai’s failure to disclose to the PTO examiner for the ‘339 application three other sets of its co-pending patent applications, all under consideration by different PTO examiners: the ‘035 application, the ‘662 application, and the ‘971 application (collectively the “other co-pending applications”). Eisai opposed Teva’s motion to amend its Answer.<sup>3</sup>

## **II. The December Order**

In the December Order, Magistrate Judge Salas granted Teva’s motion to amend only with respect to inequitable conduct based on failure to disclose the ‘459 application. In the analysis relevant to the instant appeal, Magistrate Judge Salas first ruled that Teva’s Proposed Amended Answer presented four separate allegations of inequitable conduct: non-disclosure of the ‘459 application and the three other co-pending applications. Teva claimed that it asserted only *one* basis of inequitable conduct: failure to disclose the ‘459 application. According to Teva, the failure to disclose the other co-pending applications only constituted evidence of Eisai’s intent to deceive the PTO in failing to disclose the ‘459 application, with the other non-disclosures demonstrating a “pattern of failures to disclose.” December Order, 247 F.R.D. at 451. Due to Teva’s inconsistent depiction of its allegations in the Proposed Amended Answer

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<sup>3</sup>During the pendency of the motion to amend, Teva filed its Answer to Eisai’s second Complaint (No. 07-5489). This Answer was substantially identical to the Proposed Amended Answer filed with Teva’s motion to amend in the first-filed action with regard to the inequitable conduct allegations.

and its briefs, Magistrate Judge Salas viewed Teva's effort to "blend all four co-pending applications into one allegation of inequitable conduct" as an "artful attempt" to avoid the heightened pleading standard of Federal Rule of Civil Procedure 9(b) with regard to the other non-disclosures.<sup>4</sup> *Id.* Thus, Magistrate Judge Salas examined each asserted instance of inequitable conduct separately, requiring Teva to plead fraud for each with the requisite particularity under Rule 9(b) to withstand a motion to dismiss.

Before turning to the specific allegations, Magistrate Judge Salas also limited the temporal scope of any claimed basis of inequitable conduct. Eisai's initial '339 application to the PTO was rejected by the PTO examiner, apparently for reasons not directly related to the co-pending applications allegedly withheld by Eisai during the prosecution of that initial application. (*See* Patunas Decl., Ex. B ("Proposed Amended Answer") at ¶ 43 (alleging that initial '339 application was rejected as being "anticipated and/or obvious . . . over U.S. Patent 3,746,759").) Eisai subsequently amended its '339 application to include a narrower set of claims than the initial application. This narrowed application was eventually approved by the PTO and issued as the '841 patent-in-suit. Magistrate Judge Salas deemed any inequitable conduct with regard to the *initial* '339 application irrelevant to the enforceability of the '841 patent-as-issued. Therefore, the Magistrate Judge held that only inequitable conduct allegations arising from non-disclosures during the prosecution of the *amended* '339 application would be allowed, and that leave to amend with allegations arising from conduct during the prosecution of the *initial* '339

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<sup>4</sup>Rule 9(b) states that "[i]n alleging fraud. . . , a party must state with particularity the circumstances constituting fraud," Fed. R. Civ. P. 9(b), and the Federal Circuit has held that inequitable conduct must be pled with particularity, *Ferguson Beauregard/Logic Controls, Div. of Dover Res., Inc. v. Mega Sys., LLC*, 350 F.3d 1327, 1344 (Fed. Cir. 2003).

application would be denied.

Based on these initial rulings, Magistrate Judge Salas proceeded to consider Teva's allegations with regard to each of the four co-pending applications. Although the court disallowed Teva's allegations regarding non-disclosure of the '459 application that specifically addressed the initial '339 application, it granted leave to amend with regard to the '459 application allegations that implicated conduct involving the '841 patent-as-issued, i.e., conduct regarding the amended '339 application. The Magistrate Judge emphasized that with regard to these allowable '459 application allegations, Teva pled with particularity the undisclosed prior art, knowledge of the prior art by an Eisai official, and why the undisclosed items were material. *Id.* at 451-52. With regard to the three other families of co-pending applications, Magistrate Judge Salas found Teva's allegations lacking in particularity. Teva's allegations regarding the other three sets of co-pending applications failed to include "discussion of specific claims or specific pieces of prior art" or "linkage to the '841 patent as issued." *Id.* at 452. Teva also failed to include any averment of intent to deceive with regard to the other three applications. By contrast, Teva alleged with regard to the '459 application that this "material information was withheld with an intent to deceive the PTO." (Proposed Amended Answer at ¶ 15.) Magistrate Judge Salas found this statement of intent sufficient to grant leave to Teva to amend its Answer to include its temporally relevant '459 application allegations.

### **III. Teva's Corrected Amended Answers and the February Order**

Teva did not appeal the December Opinion to this Court. Rather, on December 17, 2007,

it filed Corrected Amended Answers in an attempt to comply with the December Order.<sup>5</sup> These Corrected Amended Answers added the inequitable conduct defense solely with regard to the ‘459 application, consistent with the scope permitted by the December Order. The ‘459 application allegations included the same general averment that Eisai withheld material information “with an intent to deceive the PTO.” (Patunas Decl., Ex. C (“Corrected Amended Answer”) at ¶ 39.)<sup>6</sup>

However, Teva also included references to the other co-pending applications on which Magistrate Judge Salas had denied leave to amend. This time, Teva clarified its purpose for invoking these other co-pending applications: that collectively, they constituted a “pattern of non-disclosure” that “further supports the conclusion that the failure by Applicants to disclose the co-pending ‘459 application and Kenley was done intentionally to deceive the Examiner of the ‘339 application.” (Corrected Amended Answer at ¶ 41.) In other words, Teva converted what it claimed was implicit in its Proposed Amended Answer into an explicit allegation: that the non-disclosure of the other co-pending applications constituted only evidence of intent to deceive with regard to the ‘459 application, rather than separate bases of inequitable conduct. Teva included additional allegations in its Corrected Amended Answers regarding Eisai’s “pattern of

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<sup>5</sup>These Corrected Amended Answers also effectively withdrew the affirmative defense of obviousness. Based on this withdrawal and the parties’ prior stipulation of infringement, the only remaining liability issue in this case is inequitable conduct. In addition, Teva filed Corrected Amended Answers in both Civil Action Nos. 05-5727 and 07-5489. Shortly after Teva filed these Corrected Amended Answers, Magistrate Judge Salas entered an Order consolidating the two cases. (Doc. No. 113.)

<sup>6</sup>In this Opinion, this Court will cite to the Corrected Amended Answer filed in No. 05-5727. The Corrected Amended Answer in No. 07-5489 contains different numbering, but its inequitable conduct allegations are identical to the Corrected Amended Answer in No. 05-5727.



filing and prosecuting a series of overlapping patent applications” and a “pattern of conduct.” (*Id.* at ¶¶ 31, 32, 40.) The Corrected Amended Answers did not contain any specific allegation that the other co-pending applications were “material.” Teva merely alleged that the other co-pending applications had “claims overlapping those of the ‘459 and ‘339 applications,” that they were all assigned to different PTO examiners, and that Eisai did not disclose any of them to any of the other examiners handling any of the other applications. (*Id.* at ¶ 41.) Complaining that these allegations regarding the other co-pending applications and a “pattern of conduct” exceeded the scope of allegations permitted by the December Order, Eisai moved to strike these allegations (Paragraph 31 and portions of Paragraphs 32, 40, and 41) pursuant to Federal Rule of Civil Procedure 12(f).

In the February Order, Magistrate Judge Salas granted Eisai’s motion. First, the court specifically applied the particularity requirement of Rule 9(b) to both elements of inequitable conduct, materiality and intent. February Order, 557 F. Supp. 2d at 493 (“Under Fed. R. Civ. P. 9(b), *each element* must be plead with particularity.”) (emphasis added). Next, Magistrate Judge Salas construed Teva’s argument in opposition to Eisai’s motion to strike in the same way that she interpreted Teva’s argument on its prior motion to amend. The court acknowledged that Teva pled the non-disclosure of the other co-pending applications only as evidence of facts and circumstances from which intent to deceive could be inferred with regard to the ‘459 application. In the Magistrate Judge’s words, “Teva wants to use the other applications as atmospherics to help it prove intent to deceive.” *Id.* However, the court construed Teva’s argument as also advancing the notion that the other co-pending applications were material. *Id.* (“Teva’s brief begins with a claim that the co-pending applications only speak to intent but ends with an

argument as to their materiality.”). After this discussion of Teva’s purportedly conflicting arguments, Magistrate Judge Salas essentially reasoned that allegations of non-disclosure of co-pending applications are allowable to show intent to deceive *only* if the non-disclosure was material and if that materiality is pled with particularity:

[T]he fact of the matter is that co-pending applications are only relevant insofar as they are material. Without alleging materiality, Teva has no basis upon which to assert that the co-pending applications should have been disclosed to the patent examiner. It follows that those co-pending applications do not evidence an intent to deceive and cannot be used in that manner. As Eisai argues, “[o]ne cannot intend to deceive by not disclosing information not alleged to be material.” This Court agrees. Failure to alert a patent examiner to a co-pending application cannot be deceitful if the application is not material.

*Id.* at 493-94 (internal citation omitted). Magistrate Judge Salas finally observed that all of the cases Teva cited to support its theory actually stood for the opposite proposition, namely that “co-pending applications, when used as evidence of an intent to deceive, must be material.” *Id.* at 494. Teva appealed the February Order to this Court (Doc. No. 157).<sup>7</sup>

#### **IV. May Bench Order**

While Teva’s appeal of the February Order was pending, the parties engaged in discovery. Teva served Eisai with certain discovery requests. Teva’s Interrogatory 17, Rule 30(b)(6) deposition topic 4, and Document Request 79 sought information regarding 1) the other co-pending applications struck by Magistrate Judge Salas in the February Order; and 2) other patent applications filed by Eisai that had been abandoned over a six-year period culminating in

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<sup>7</sup> On the same date that Teva filed its appeal, it filed its Second Corrected Amended Answer in which it complied with Magistrate Judge Salas’s two orders by removing any references to the other co-pending applications and focusing solely on inequitable conduct based on failure to disclose the ‘459 application.

the issuance of the patent-in-suit. As Teva conceded at oral argument before the Magistrate Judge, Teva's right to conduct discovery with regard to the other co-pending applications depended upon this Court's reversal of the February Order.

From the bench on May 29, 2008, Magistrate Judge Salas orally denied without prejudice Teva's motion to compel discovery with respect to the other co-pending applications. Magistrate Judge Salas viewed the discovery requests regarding abandoned applications as new, i.e., not raised in the previous motion to amend or the motion to strike. Therefore, Magistrate Judge Salas denied requests on this related topic, reasoning that this request "would fall outside the scope of discovery permitted, even if Judge Ackerman reverses this Court." (Michael Decl., Ex. 1 (Tr. 5/29/08) at 99:16-18.) Teva appealed both of these denials to this Court (Doc. No. 201).

### *Analysis*

#### **I. Standard of Review**

Pursuant to 28 U.S.C. § 636(b)(1)(A), Federal Rule of Civil Procedure 72(a), and Local Civil Rule 72.1(a), a United States Magistrate Judge may hear non-dispositive motions. On appeal, a district court may modify or set aside a magistrate judge's non-dispositive order if the ruling was "clearly erroneous or contrary to law." Fed. R. Civ. P. 72(a); L. Civ. R. 72.1(c)(1)(A); *see also Haines v. Liggett Group Inc.*, 975 F.2d 81, 91 (3d Cir. 1992); *Cipollone v. Liggett Group, Inc.*, 785 F.2d 1108, 1113 (3d Cir. 1986). A ruling is clearly erroneous "when although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed." *Dome Petroleum Ltd. v. Employers Mut. Liab. Ins. Co.*, 131 F.R.D. 63, 65 (D.N.J. 1990) (quoting *United States v. U.S. Gypsum Co.*,

333 U.S. 364, 395 (1948)). A magistrate judge's order is contrary to law "when the magistrate judge has misinterpreted or misapplied the applicable law." *Doe v. Hartford Life & Accident Ins. Co.*, 237 F.R.D. 545, 548 (D.N.J. 2006) (citing *Pharm. Sales & Consulting Corp. v. J.W.S. Delavau Co.*, 106 F. Supp. 2d 761, 764 (D.N.J. 2000)). While a magistrate judge's decision typically is entitled to deference, "a magistrate judge's legal conclusions on a non-dispositive motion will be reviewed de novo." *Id.*

## **II. This Court Will Reverse the February Order**

In granting Eisai's motion to strike, Magistrate Judge Salas misapplied Rule 9(b). Furthermore, Federal Circuit precedent does not foreclose Teva from supporting its allegations of intent as it proposes with a prior pattern of non-disclosures. This Court cannot say, as a matter of law, that Teva's allegations have no possible relation to its defense. Therefore, the drastic remedy of striking allegations was not warranted. Although, as this Court will discuss, this error is understandable in the context of this complicated case, this Court is duty-bound to reverse the February Order as contrary to law.

### A. Rule 12(f)

Teva's appeal of the February Order requires this Court to review Magistrate Judge Salas's grant of Eisai's Rule 12(f) motion to strike. Rule 12(f) provides the means to challenge the sufficiency of affirmative defenses. *See Mars Inc. v. JCM Am. Corp.*, No. 05-3165, 2006 WL 1704469, at \*3 (D.N.J. Jun. 14, 2006). In deciding a Rule 12(f) motion, a court "may strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." Fed. R. Civ. P. 12(f). This standard essentially translates into application of the standards of a Rule 12(b)(6) motion to dismiss, with the understanding that a motion to strike

should be granted sparingly. *See Mars*, 2006 WL 1704469, at \*4; *see also Symbol Techs., Inc. v. Aruba Networks, Inc.*, 609 F. Supp. 2d 353, 356 (D. Del. 2009).

Motions to strike are highly disfavored. *See Garlanger v. Verbeke*, 223 F. Supp. 2d 596, 609 (D.N.J. 2002); *Tonka Corp. v. Rose Art Indus., Inc.*, 836 F. Supp. 200, 217 (D.N.J. 1993). Striking a pleading is a “drastic remedy to be resorted to only when required for the purposes of justice.” *Tonka Corp.*, 836 F. Supp. at 217 (quotation and citation omitted). Here, Eisai did not seek to strike Teva’s *entire* inequitable conduct defense as “insufficient.” Instead, Eisai moved to strike Teva’s individual allegations regarding the pattern of non-disclosure of other co-pending applications. In such a situation, courts do not grant motions to strike unless the moving party shows that “the allegations have no possible relation to the controversy and may cause prejudice to one of the parties, or if the allegations confuse the issues.” *Garlanger*, 223 F. Supp. 2d at 609 (D.N.J. 2002) (quoting *Tonka Corp.*, 836 F. Supp. at 217); *see also DeLa Cruz v. Piccari Press*, 521 F. Supp. 2d 424, 428 (E.D. Pa. 2007). “When faced with allegations that could possibly serve to achieve a better understanding of plaintiff’s claims or perform any useful purpose in promoting the just disposition of the litigation, courts generally deny such motions to strike.” *Del. Health Care Inc. v. MCD Holding Co.*, 893 F. Supp. 1279, 1292 (D. Del. 1995) (quoting 5A Charles A. Wright & Arthur R. Miller, *Federal Practice and Procedure* § 1382, at 695-96 (2d ed. 1990)). Under the “strict” standard of Rule 12(f), “only allegations that are so unrelated to plaintiffs’ claims as to be unworthy of any consideration should be stricken.” *Johnson v. Anhorn*, 334 F. Supp. 2d 802, 809 (E.D. Pa. 2004) (internal quotation and citation omitted).

Furthermore, Rule 12(f) motions often will not be granted where the challenged allegations depend on disputed issues of fact, due to the “practical difficulty of deciding cases

without a factual record.” *Tonka Corp.*, 836 F. Supp. at 217 (quotation and citation omitted); *see also United States v. Sensient Colors, Inc.*, 580 F. Supp. 2d 369, 374 (D.N.J. 2008) (noting reluctance of courts to grant Rule 12(f) motions “out of a concern that they often involve a premature evaluation of a defense’s merits”). Even if facts are not in dispute, courts should not use a Rule 12(f) motion “to determine disputed and substantial questions of law.” *Tonka Corp.*, 836 F. Supp. at 218.

#### B. Inequitable Conduct

Determination of the relevance of Teva’s allegations, and whether they were pled sufficiently, requires an understanding of the law of inequitable conduct. “A patent may be rendered unenforceable for inequitable conduct if an applicant, with intent to mislead or deceive the examiner, fails to disclose material information or submits materially false information to the PTO during prosecution.” *Larson Mfg. Co. of S.D., Inc. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1326 (Fed. Cir. 2009) (quotation and citation omitted). The defense therefore has two elements: materiality and intent. *Id.* Information is material “when a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent.” *Id.* (quotation and citations omitted).

The Federal Circuit has instructed that “[t]o satisfy the intent to deceive element of inequitable conduct, ‘the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive.’” *Impax Labs., Inc. v. Aventis Pharms. Inc.*, 468 F.3d 1366, 1374-75 (Fed. Cir. 2006) (quoting *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988) (en banc in relevant part)). “[I]ntent to deceive is generally inferred from the facts and

circumstances surrounding the applicant's overall conduct.” *Id.* at 1375. “[D]irect evidence of intent is unavailable in most cases and unnecessary in any event.” *Frazier v. Roessel Cine Photo Tech, Inc.*, 417 F.3d 1230, 1235 (Fed. Cir. 2005). Because such direct, “smoking gun” evidence may rarely be found, “intent may be inferred from the surrounding circumstances.” *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1256 (Fed. Cir. 1997).

C. The December Order Did Not Resolve the Issue Presented in This Appeal

At the outset, this Court rejects Eisai's contention that Teva's failure to appeal the December Order prevents it from seeking to include the intent allegations at issue and precludes this appeal. In its initial motion to amend, Teva contended that it asserted one single basis of inequitable conduct: the failure to disclose the '459 application. The allegations in its Proposed Amended Answer regarding the other co-pending applications, according to Teva, served only as support for the required element of intent to deceive with regard to the failure to disclose the '459 application. However, Teva framed these allegations in its Proposed Amended Answer with the use of separate headings for each co-pending application and the mere allegation that each was “material.” This Court agrees with Magistrate Judge Salas's reasonable conclusion in the December Order that Teva's pleading appeared to assert that each “presents a new and separate instance of inequitable conduct.” 247 F.R.D. at 451.

Teva did not appeal this ruling, and thus Teva accepted Magistrate Judge Salas's conclusion that it had pled four independent bases of inequitable conduct, and that it failed to plead adequately the ones involving non-disclosure of the other co-pending applications. In its Corrected Amended Answers filed after the December Order, Teva attempted to clarify the purpose for its invocation of the other co-pending applications. Teva carefully limited its

allegations regarding the other co-pending applications such that they only serve to support intent, rather than provide independent bases of inequitable conduct. Magistrate Judge Salas viewed these renewed allegations with suspicion, as they appeared to the court to recycle the “single basis of inequitable conduct” argument that she rejected in the December Order.

However, the Magistrate Judge in the December Order did not specifically hold that allegations regarding the other co-pending applications were irrelevant to Eisai’s *intent* to deceive in relation to the allowed basis for inequitable conduct: the failure to disclose the ‘459 application. The court only held that the allegations concerning the other co-pending allegations could not stand alone as separate instances of fraud in the prosecution of the ‘841 patent such that they could be invoked separately to render the ‘841 patent unenforceable.

Therefore, Teva’s failure to appeal the December Order does not foreclose the instant appeal of the February Order. Only in the February Order did the Magistrate Judge rule that the allegations concerning the other co-pending applications were insufficient as indicia of intent. However, by applying a heightened pleading standard to these allegations, and deeming them irrelevant to Teva’s defense, the Magistrate Judge erred as a matter of law.

#### D. Rule 9(b)

Rule 9(b) states that “[i]n alleging fraud . . . , a party must state with particularity the *circumstances constituting fraud*.” Fed. R. Civ. P. 9(b) (emphasis added). The Federal Circuit has held that inequitable conduct must be pled in accordance with the heightened pleading standard of Rule 9(b). *Ferguson Beauregard/Logic Controls, Div. of Dover Res., Inc. v. Mega Sys., LLC*, 350 F.3d 1327, 1344 (Fed. Cir. 2003) (stating that “inequitable conduct, while a broader concept than fraud, must be pled with particularity”). This Court must apply Federal



Circuit law to assess the sufficiency of inequitable conduct pleadings. *See Cent. Admixture Pharm. Servs., Inc. v. Advanced Cardiac Solutions, P.C.*, 482 F.3d 1347, 1356 (Fed. Cir. 2007) (“Whether inequitable conduct has been adequately pled is a procedural matter, but since it bears on an issue that ‘pertains to or is unique to patent law,’ we will apply our own law to the question of whether the pleadings were adequate.”) (quoting *Intel Corp. v. Commonwealth Sci. & Indus. Res. Org.*, 455 F.3d 1364, 1369 (Fed. Cir. 2006)).

Magistrate Judge Salas held that Teva must plead *both* elements of inequitable conduct – materiality *and* intent – with particularity. February Order, 557 F. Supp. 2d at 493. Courts have not always clearly defined how Rule 9(b) applies to intent allegations in inequitable conduct cases. *See Mars*, 2006 WL 1704469, at \*7 (discussing cases in which courts “did not discuss any pleading requirements regarding the intent to deceive element of inequitable conduct” and did not “mention . . . the intent to deceive element or its relevance to the 9(b) requirements”); *see also Vita-Mix Corp. v. Basic Holdings, Inc.*, No. 06-2622, 2007 WL 2816209, at \*5 (N.D. Ohio Sept. 27, 2007) (“Courts have struggled with whether or not the intent to deceive must be specifically alleged and, if so, what words will constitute sufficient pleading.”). This Court concludes, based on the plain text of the Rule and its application by various courts, that allegations supporting intent need not be pled with the substantive particularity required by the February Order. In asserting prior non-disclosures solely to help show intent, a party need not allege those prior non-disclosures were material.

While Rule 9(b) requires the “circumstances constituting fraud” to be pled with particularity, the Rule also states that “intent . . . and other conditions of a person’s mind may be alleged generally.” Fed. R. Civ. P. 9(b). The court did not cite this latter portion of Rule 9(b)

regarding state of mind. This Court reads the plain text of the Rule to state that intent need not be pled with any substantive particularity.

This Court's review of the relevant caselaw reinforces its reading of the Rule. In *Central Admixture*, the Federal Circuit affirmed a district court's dismissal of an inequitable conduct defense based on non-compliance with Rule 9(b), faulting the defendant's pleading because it "fail[ed] to provide the required particularity to give notice to the other party of the facts on which the defense is premised." 482 F.3d at 1357. The defendant in *Central Admixture* pled inequitable conduct "by alleging only that 'during prosecution of the [] patent, the patentee failed to disclose all of the relevant prior art known to it' and that 'by manipulation of various measurements and units, the patentee sought to mislead the [PTO] regarding the relationship between the claimed invention and the prior art.'" *Id.* at 1356 (quoting defendant's Answer). The Federal Circuit found these allegations to lack the "requisite particularity" because the pleadings did "not identify what relevant and undisclosed prior art was known to the patentee, what 'measurements and units' were manipulated, or how that manipulation was meant to mislead the PTO." *Id.* at 1356-57. While the reference in *Central Admixture* to "how that manipulation was meant to mislead the PTO," read in isolation, could suggest a requirement that intent be pled with some substantive particularity, that case's context and its subsequent application strongly indicates that the quoted language pertains to the materiality of the manipulation to the patent-at-issue, and not to the defendant's state of mind. Indeed, the court in *Central Admixture* did not refer to "intent" at all. Courts have routinely held that a party asserting inequitable conduct must only plead with particularity the circumstances of the fraud – the content and substance of the misrepresentation or omission, the actors who committed the

fraud, and the conduct's materiality to the patent-at-issue – to satisfy Rule 9(b).<sup>8</sup>

Magistrate Judge Salas imposed a higher pleading standard on Teva's intent allegations concerning the other co-pending applications by requiring those intent allegations to be pled with particularity, and specifically by requiring that the intent allegations include particularized allegations of materiality. The particularity standard of Rule 9(b) has been applied to require more than "vague allegations of fraud and deception," and to "instead . . . specify the time, place and content of any alleged misrepresentations to the PTO." *Sun Microsystems, Inc. v. Dataram Corp.*, No. 96-20708, 1997 WL 50272, at \*4 (N.D. Cal. Feb. 4, 1997). Such circumstances do

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<sup>8</sup>See, e.g., *Probert v. Clorox Co.*, No. 07-139, 2009 WL 1011490, at \*4 (D. Utah Apr. 15, 2009) ("In the proposed counterclaim, Defendant has sufficiently identified the alleged inequitable conduct, the actors who committed the alleged inequitable conduct, and the time frame in which the alleged inequitable conduct occurred."); *Applera Corp. v. Michigan Diagnostics, LLC*, 594 F. Supp. 2d 150, 163-64 (D. Mass. 2009) (dismissing inequitable conduct claim because defendant "specifie[d] neither the particular patents that it believes were obtained through fraud or inequitable conduct, nor the prior art . . . that should have been disclosed to the PTO."); *TASER Int'l, Inc. v. Stinger Sys., Inc.*, No. 07-42, 2008 WL 4183019, at \*7 (D. Ariz. Sept. 8, 2008) (holding that defendant, unlike defendant in *Central Admixture*, "has alleged more than mere conclusory allegations of fraud, and has identified [defendant], and thus the inventors of the patents in questions and their attorneys and agents, as the individuals that have breached the duty of candor to the PTO, and the prior art which was allegedly withheld from the PTO"); *Hertz Corp. v. Enterp. Rent-A-Car Co.*, 557 F. Supp. 2d 185, 194 (D. Mass. 2008) ("The court is satisfied that plaintiffs have met their burden under the heightened pleading requirements of Rule 9(b) by identifying [involved parties] by name, by specifying the allegedly perjurious documents that were submitted to the PTO, and by stating the basis for believing them to be false."); *MacLean-Fogg Co. v. Eaton Corp.*, No. 07-472, 2008 WL 941967, at \*1 (E.D. Tex. Apr. 7, 2008) (denying motion to strike inequitable conduct defense where defendant's pleading "detail[ed] the time, place, speakers, and contents of the inequitable conduct, which is sufficient to give notice to [plaintiff]"); *Applied Interact, LLC v. Cont'l Airlines, Inc.*, No. 07-341, 2008 WL 177740, at \*7-\*9 (E.D. Va. Jan. 17, 2008) (requiring inequitable conduct pleading to allege the time and place of the conduct, the parties responsible, and the contents of the conduct; striking defense for not specifying the material information that was withheld); *Multimedia Patent Trust v. Microsoft Corp.*, 525 F. Supp. 2d 1200, 1212 (S.D. Cal. 2007) ("As opposed to the pleading found deficient in [*Central Admixture*], Defendants identified the inventors and their attorneys and agents as the individuals who breached their duty of candor to the PTO, and the prior art which was allegedly withheld from the PTO.").

not include particularized allegations of intent.<sup>9</sup>

Some courts have required that an inequitable conduct pleading state “specifically” that the patent owner had an intent to deceive the PTO by literally including the words “intent to deceive.” *Collaboration Props. Inc. v. Tandberg ASA*, No. 05-1940, 2007 WL 205065, at \*3-\*4 (N.D. Cal. Jan. 25, 2007); *see also Xilinx, Inc. v. Altera Corp.*, No. 93-20709, 1994 WL 782236, at \*3 (N.D. Cal. Feb. 8, 1994) (stating that if defendant “believes it can later prove that [plaintiff] intended to deceive the PTO – whether through direct or circumstantial evidence – [defendant’s] pleading should, at the very least, reflect that belief”). This specific pleading requirement has been met here, as Teva alleged in its Corrected Amended Answers that Eisai withheld the ‘459 application “with an intent to deceive the PTO.” (Corrected Amended Answer at ¶ 39.)<sup>10</sup>

Beyond a specific pleading of intent to deceive, however, courts have not imposed any particularity requirement for intent. Courts have only applied a particularity standard to the materiality element. *See, e.g., Collaboration Props.*, 2007 WL 205065, at \*3 (“To plead an inequitable conduct claim, a party must set forth the content of the alleged misrepresentation or omission and indicate why or how the alleged misrepresentation or omission is material.”).

Where courts discuss the standard for pleading intent at all beyond an averment of “intent to

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<sup>9</sup>Although this Court does not apply Third Circuit law to this question because Federal Circuit law controls, this standard comports with our Circuit’s reading of Rule 9(b). To satisfy the strictures of Rule 9(b) in our Circuit, a party alleging fraud “must state the circumstances of the alleged fraud with sufficient particularity to place the defendant on notice of the ‘precise misconduct with which [it is] charged.’” *Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir. 2007) (quoting *Lum v. Bank of Am.*, 361 F.3d 217, 223-224 (3d Cir. 2004)).

<sup>10</sup>Indeed, in the December Order, Magistrate Judge Salas properly rejected Teva’s inequitable conduct allegations with regard to the other co-pending applications in part for a similar failure even to use the words “intent to deceive” with regard to those applications.

deceive,” these courts merely acknowledge that intent is often proved by inferences and surrounding circumstances. *See, e.g., TASER Int’l, Inc. v. Stinger Sys., Inc.*, No. 07-42, 2008 WL 4183019, at \*6 (D. Ariz. Sept. 8, 2008) (“In addition, matters of intent may be averred generally under Fed. R. Civ. P. 9(b); ‘intent to deceive is generally inferred from the facts and circumstances surrounding a knowing failure to disclose material information.’”) (quoting *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd.*, 394 F.3d 1348, 1354 (Fed. Cir. 2005)).

Requiring heightened pleading with regard to intent “would not serve to further the aims of the heightened pleading standard, which is to discourage bald assertions of fraudulent misconduct without sufficient factual underpinnings.” *Vita-Mix Corp. v. Basic Holdings, Inc.*, No. 06-2622, 2007 WL 2816209, at \*5 (N.D. Ohio Sept. 27, 2007) (declining even to require inclusion of words “intent to deceive” in inequitable conduct pleading where defendants specifically identified prior art knowingly withheld). In *Mars Inc. v. JCM American Corp.*, after canvassing the relevant caselaw regarding the pleading standard for inequitable conduct, a court in this District denied a motion to strike where the defendants’ allegations contained “some measure of substantiation and precision” in that they provided “the name of the prior relevant art and the acts of alleged fraud.” *Mars*, 2006 WL 1704469, at \*8. In moving to strike, the plaintiff in *Mars* contended that the defendant failed to allege intent sufficiently, but the court concluded that the plaintiff’s argument “would be more appropriately raised in summary judgment motions or at trial.” *Id.* at \*9.

This Court agrees with the approach of the court in *Mars*. Teva’s Corrected Amended Answers contained a general averment of “intent to deceive,” along with detailed, particularized allegations regarding the circumstances of the fraud: the non-disclosure of the ‘459 application,

knowledge of that application by Eisai, and the materiality of that application to the ‘841 patent-as-issued. Rule 9(b) simply does not require anything more particular with regard to intent at the pleading stage, and Teva’s allegations “provide the required particularity to give notice to the other party of the facts on which the defense is premised.” *Cent. Admixture*, 482 F.3d at 1357. Magistrate Judge Salas misapplied Rule 9(b) in requiring that Teva’s intent allegations regarding the other co-pending applications be supported by particularized pleadings of materiality.

E. The Relevance of a Pattern of Prior Non-Disclosure to Showing Intent

In addition to requiring intent to be pled with particularity, the Magistrate Judge concluded that “co-pending applications are only relevant insofar as they are material,” because “[w]ithout alleging materiality, Teva has no basis upon which to assert that the co-pending applications should have been disclosed to the patent examiner.” February Order, 557 F. Supp. 2d at 493-94. The court therefore held that the challenged intent allegations “do not evidence an intent to deceive” and are irrelevant to Teva’s defense. *Id.* at 494. While the allegations might ultimately not support a finding of intent to deceive because the prior non-disclosures were not material at the time of those non-disclosures, the allegations cannot be rejected at the pleading stage under Rule 12(f). Striking these allegations unduly limits Teva’s efforts to prove intent to deceive. Federal Circuit law, including those cases cited in the February Order, cannot be read to *preclude* use of a prior pattern of conduct to bolster other evidence of intent. This Court strongly doubts that Eisai’s alleged “pattern of initial non-disclosures,” if proven and standing alone, could suffice to show intent to deceive. However, this Court is not convinced that the type of evidence Teva seeks to produce is so irrelevant to intent that pleadings regarding that evidence should have been stricken from the Corrected Amended Answers.

The Magistrate Judge relied on several cases that the court read as “agree[ing] with the fundamental proposition that co-pending applications, when used as evidence of intent to deceive, must be material.” *Id.* at 494 (citing cases). These cases focused on attempts to prove intent to deceive based on the circumstances surrounding the actual non-disclosure that formed the basis for the inequitable conduct, including the materiality of that non-disclosure. *See Semiconductor Energy Lab. Co. v. Samsung Elecs. Co.*, 204 F.3d 1368, 1377 (Fed. Cir. 2000); *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1256-59 (Fed. Cir. 1997); *Nisus Corp. v. Perma-Chink Sys., Inc.*, No. 03-120, 2006 WL 2128903, at \*4 (E.D. Tenn. July 27, 2006). The degree of materiality of the non-disclosure affects the intent inquiry, because the higher the materiality, the stronger the inference of intent to deceive. *See Eisai Co., Ltd. v. Teva Pharms. USA, Inc.*, No. 05-5727, 2008 WL 1722098, at \*5 (D.N.J. Mar. 28, 2008) (Ackerman, J.) (citing *Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1367 (Fed. Cir. 2007); *GFI, Inc. v. Franklin Corp.*, 265 F.3d 1268, 1273 (Fed. Cir. 2001)). Therefore, parties asserting inequitable conduct based on non-disclosure of prior art necessarily use evidence regarding that prior art to show materiality and to prove intent based in part on materiality.

The cases cited in the February Order indeed “use a pattern of failing to disclose *material* information as evidence of intent to deceive.” February Order, 557 F. Supp. 2d at 494 (emphasis in original). However, all these cases involve final rulings on the defense of inequitable conduct after a bench trial. *See Semiconductor Energy*, 204 F.3d at 1371; *Critikon*, 120 F.3d at 1255 (Fed. Cir. 1997); *Nisus*, 2006 WL 2128903, at \*2. These cases do not address the initial pleading requirements for a pattern of non-disclosure as evidence to bolster an inference of intent to deceive. Furthermore, they do not preclude the use – to help prove intent to deceive – of a prior

pattern of non-disclosure of information at a prior time when that information was material, because this issue was not presented in these cases. Indeed, these cases simply do not discuss any pattern of *prior* conduct with regard to intent, presumably because this issue was not raised, and these cases certainly do not bar use of such prior conduct. *See Semiconductor Energy*, 204 F.3d at 1377; *Critikon*, 120 F.3d at 1256-57; *Nisus*, 2006 WL 2128903, at \*4.<sup>11</sup>

A recent Federal Circuit decision suggests that a prior pattern of non-disclosure, if proven, could be relevant to intent to deceive. In affirming a finding of no inequitable conduct based on a lack of intent to deceive, the Federal Circuit in *Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc.* highlighted the patentee's "highly consistent pattern of disclosing references [with a certain common feature] in the prosecution of hundreds of its other patent applications." 518 F.3d 1353, 1367 (Fed. Cir. 2008). The court in *Pfizer* viewed this pattern of disclosure in other patent prosecutions as supporting the patentee's asserted good faith basis for the non-disclosure that formed the basis of defendant's inequitable conduct allegation. *Id.* (observing that the district court "credited this 'highly consistent pattern' as strong evidence supporting [plaintiff's] good faith explanation for not disclosing the [] references"). Thus, the Federal Circuit's indication in *Pfizer* that a pattern of material disclosure in other prosecutions is relevant to prove lack of intent to deceive strongly indicates that an alleged pattern of *non*-disclosure could be relevant to establish intent to deceive, if proven and if material.

Eisai relies on *Kimberly-Clark Corp. v. Johnson & Johnson*, in which the Federal Circuit

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<sup>11</sup>The court in *Nisus* discussed an "ongoing pattern of failures" as supporting intent to deceive. However, the pattern referenced by the court constituted the conduct that formed the basis of inequitable conduct defense, not an additional, prior pattern as implicated here. *Nisus*, 2006 WL 2128903, at \*4.



stated that “the key issues of materiality and intent should be decided with reference to the claims of the patent.” 745 F.2d 1437, 1457 (Fed. Cir. 1984). This statement could be construed as requiring that non-disclosure of a co-pending application, when used solely as evidence of intent, must be material to the patent-as-issued. In *Kimberly-Clark*, the Federal Circuit criticized the defendants’ attempt “to build a case of ‘fraud’ by reason of non-disclosure of prior art material only to abandoned claims long since cancelled during prosecution after being rejected by the examiner as unpatentable for reasons not involving the uncited prior art.” *Id.* The court explained that “[t]o base a conclusion of ‘fraud’ on such grounds is to deal with a hypothetical situation, not with reality.” *Id.* However, Eisai “excerpt[s] too little and makes too much of the statement in *Kimberly-Clark*.” *Fox*, 922 F.2d at 803.

Most importantly, *Kimberly-Clark* involved an appeal from a final judgment on inequitable conduct following a bench trial, and did not address whether intent needed to be *pled* with particularized reference to the claims of the patent, i.e. with reference to materiality. *Id.* at 1440. Furthermore, the opinion makes clear that in this statement, the Federal Circuit was addressing the circumstances of the fraud itself, not intent *per se*. The court commented that, with regard to inequitable conduct, defendants “had little or nothing to say” about the claims of the patent, and that they did not show that “non-disclosure of prior art would have had any effect” on whether that patent would have issued. *Id.* This reasoning illustrates that the defendants in *Kimberly-Clark* sought to base their inequitable conduct defense *entirely* on non-disclosures relevant to the initial application, and failed to present any evidence of non-disclosure of information material to the patent-as-issued. See *Fox Indus., Inc. v. Structural Preservation Sys., Inc.*, 922 F.2d 801, 803 (Fed. Cir. 1990) (distinguishing *Kimberly-Clark* by observing that

in *Kimberly-Clark*, “the non-disclosed prior art was not material to the allowed claims”).<sup>12</sup>

That situation differs greatly from the instant case, aside from the different stages of the two litigations. Here, Teva does not seek to build a case of fraud *solely* by reason of non-material non-disclosures. Teva bases its inequitable conduct defense on the non-disclosure of the ‘459 application, and Magistrate Judge Salas correctly held that Teva has sufficiently alleged the materiality of this non-disclosure to the ‘841 patent-as-issued. Teva has much to say about the effect of the non-disclosure of the ‘459 application on the claims finally patented in the ‘841 patent. It only raises the other co-pending applications as additional evidence to support intent, and seeks to show that the non-disclosures of the other co-pending applications were material at the time of the non-disclosures. At this stage, this Court must focus on the sufficiency of Teva’s *allegations*, not what it might ultimately prove.

Magistrate Judge Salas struck Teva’s challenged allegations because they did not plead materiality, either to the patent-as-issued or at some prior time. Yet, as discussed above, Rule 9(b) does not require any such particularized pleading for intent allegations, even if an eventual showing of materiality might be essential for the relevance of the evidence. The Federal Circuit has not held that a prior pattern of non-disclosure is irrelevant to intent to deceive. Such a pattern could be relevant, at a minimum, to intent as part of consideration of the surrounding circumstances.

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<sup>12</sup>The Federal Circuit has cited *Kimberly-Clark* for the notion that “materiality and intent to deceive are necessarily intertwined.” *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, 525 F.3d 1334, 1344 (Fed. Cir. 2008). However, rather than expand the reach of its reasoning in *Kimberly-Clark*, the Federal Circuit has narrowed its scope to allow, under certain circumstances, consideration of non-disclosures material to subsequently cancelled or amended claims. See *Baxter Int’l, Inc. v. McGaw, Inc.*, 149 F.3d 1321, 1331-32 (Fed. Cir. 1998); *Fox*, 922 F.2d at 803.

At the pleading stage, on a Rule 12(f) motion, mere relevance is sufficient, as this Court cannot say that these allegations “have no possible relation to the controversy.” *Garlanger*, 223 F. Supp. 2d at 609 (quoting *Tonka Corp.*, 836 F. Supp. at 217). These allegations, if properly proven, “could possibly serve to achieve a better understanding of plaintiff’s claims or perform any useful purpose in promoting the just disposition of the litigation.” *Del. Health Care*, 893 F. Supp. at 1292 (quoting 5A Wright & Miller § 1382, at 695-96). The parties’ factual dispute over the materiality of the asserted prior pattern of conduct, and the Federal Circuit’s near silence on the substantial question of law regarding the relevance to intent of a prior pattern of conduct, further counsels against striking Teva’s allegations. *See Sensient Colors*, 580 F. Supp. 2d at 374; *Tonka Corp.*, 836 F. Supp. at 217-18. The Magistrate Judge’s conclusion in the February Order, in addition to misapplying Rule 9(b), amounted to a holding that Teva’s allegations were “so unrelated to plaintiffs’ claims as to be unworthy of any consideration.” *Johnson*, 334 F. Supp. 2d at 809. The Magistrate Judge’s decision was contrary to Rule 9(b) and the law governing Rule 12(f) motions.

#### F. Conclusion

While this Court concludes that Magistrate Judge Salas erred in granting Eisai’s motion to strike, the Magistrate Judge’s decision reflects a justified concern that Teva sought to make an end-run around Rule 9(b) by belatedly recycling insufficient inequitable conduct claims as thinly-supported indicia of intent. Due to the Federal Circuit’s highly critical view of specious allegations of inequitable conduct, *see, e.g., Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988), strict application of Rule 9(b) – as Magistrate Judge Salas properly stated – helps guard against “the potential fishing expedition brought on by vague allegations of

inequitable conduct,” December Order, 247 F.R.D. at 450 n.3. However, motions to strike are also highly disfavored, and the heightened pleading standard of Rule 9(b) cannot be extended to require particularized pleadings of materiality to support allegations directed only to intent.

This Court shares the Magistrate Judge’s evident reluctance to allow unwarranted exploration of rather thin allegations, but concludes that Teva should be permitted, within the limits of the law, to develop its case for intent to deceive in this complex case. Nevertheless, this Court expects the parties to litigate this issue without succumbing to the unwelcome distraction of an extended fishing expedition resulting in a virtual side-trial on prior co-pending applications relevant only to intent. The parties should focus at all times on the only asserted basis of inequitable conduct here – the failure to disclose the ‘459 application – and the relevance of the other co-pending applications to intent to deceive with regard to this sole basis of inequitable conduct.

This Court will reverse the Magistrate Judge’s February Order and refer this matter to Magistrate Judge Salas for further case management proceedings consistent with this Opinion.

### **III. This Court Will Vacate the Appealed Portions of the May Bench Order**

Because this Court will reverse the February Order, this Court will also vacate the appealed portions of Magistrate Judge Salas’s May Bench Order. Teva appeals Magistrate Judge Salas’s denial of its motion to compel discovery with respect to the other co-pending applications and with respect to other applications filed by Eisai but later abandoned. First, Magistrate Judge Salas denied Teva’s motion to compel discovery regarding the other co-pending applications without prejudice, observing that “discovery as to those applications would be in play” if this Court reversed the February Order. (Michael Decl., Ex. 1 (Tr. 5/29/08) at 99:9-11.) Because this

Court will reverse the February Order, this Court will vacate the Magistrate Judge's decision on this issue.

Next, the Magistrate Judge viewed the abandoned applications issue as not affected by the pending appeal, finding that it "[fell] outside the scope of discovery permitted, even if Judge Ackerman reverses this Court." (*Id.* at 99:16-17.) Teva's discovery request sought information about abandoned applications to determine whether the prosecution of those applications might have involved non-disclosure of information material at that time, and therefore could conceivably support Teva's "pattern of non-disclosure" theory of intent. While Teva's discovery request in this regard appears speculative, this Court will vacate the decision on this issue to allow for full reconsideration at this stage and in light of this Opinion.

This Court expresses no view on the permissibility or scope of discovery regarding the two issues implicated in Teva's appeal of the May Bench Order. A magistrate judge's ruling on a non-dispositive matter such as a discovery motion is "entitled to great deference and is reversible only for abuse of discretion." *Kresefky v. Panasonic Commc'ns & Sys. Co.*, 169 F.R.D. 54, 64 (D.N.J. 1996). This Court will refer this matter to Magistrate Judge Salas for further proceedings consistent with this Opinion, mindful of the great deference owed to the Magistrate Judge's discovery and case management decisions.

#### **IV. This Court Will Stay Eisai's Motion for Summary Judgment**

During the pendency of the instant appeals, Eisai filed a motion for summary judgment. In opposition to Eisai's summary judgment motion, Teva argues that it has met its burden with regard to intent to deceive, but that if this Court disagrees, then this Court should deny Eisai's motion or grant a continuance to allow the discovery regarding intent denied by Magistrate Judge

Salas in the May Bench Order. (Teva Summ. J. Br. at 37.) In light of this Opinion, this Court will stay consideration of Eisai's motion for summary judgment, pending completion of any additional discovery that might be allowed. Indeed, arguments regarding the sufficiency of intent allegations "would be more appropriately raised in summary judgment motions or at trial," rather than on a motion to strike. *Mars*, 2006 WL 1704469, at \*9. Upon the close of additional discovery, if any, the Magistrate Judge shall establish a schedule for the submission of any supplementary summary judgment briefs and materials.

### ***Conclusion and Order***

For the foregoing reasons, it is hereby ORDERED that Magistrate Judge Salas's February 13, 2008 Order granting Eisai's motion to strike portions of Teva's Amended Answers is hereby REVERSED. It is hereby further ORDERED that the appealed portions of Magistrate Judge Salas's May 29, 2008 Bench Order denying Teva's motion to compel certain discovery are VACATED. Accordingly, it is hereby ORDERED that both of Teva's appeals (Doc. Nos. 157 and 201) are GRANTED. These matters are referred to the Magistrate Judge for further proceedings consistent with this Opinion. This Court hereby STAYS consideration of Eisai's motion (Doc. No. 214) for summary judgment, pending the completion of any additional discovery that Magistrate Judge Salas might order and pending submission of any supplemental briefs and materials.

Dated: July 6, 2009  
Newark, New Jersey

/s/ Harold A. Ackerman  
U.S.D.J.